DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2015

Zhuhai Siger Medical Equipment Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K142206
Trade/Device Name: Dental Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental operative unit and accessories
Regulatory Class: I
Product Code: EIA
Dated: January 21, 2015
Received: February 12, 2015

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142206

Device Name
Dental Unit

Indications for Use *(Describe)*
The Dental Unit is intended to supply power to and serve as a base for dental devices; and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K142206

510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K142206

1. **Date of Submission:** 01/20/2015

2. **Sponsor Identification**

Zhuhai Siger Medical Equipment Co., Ltd
Building 2, No. 1 Chuangxin Yi Road, Tangjiawan Town, Zhuhai City, Guangdong, China

Establishment Registration Number: Not yet registered

Contact Person: Huisheng Wang
Position: General Manager
Tel: 86 13802677946
Fax: 86 756 3881011
Email: wanghs@siger.cn

3. **Submission Correspondent**

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: Dental Unit
Proposed Device Model: U300, U500
Proposed Device Common Name: operative dental unit

Regulatory Information:
Classification Name: Unit, Operative Dental
Classification: I
Product Code: EIA
Regulation Number: 21 CFR 872.6640
Review Panel: Dental

Intended Use Statement:
"The Dental Unit is intended to supply power to and serve as a base for dental devices; and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair."

5. Predicate Device Identification

510(k) Number: K130410
Product Name: Dental Unit with Chair S2310
Manufacturer: Xianyang North West Medical Instrument (Group) Co., Ltd

6. Device Description

The proposed devices Dental Unit are well equipped dental unit, which are intended to supply power to and serve as a base for dental devices and accessories. They are intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. The products are attached with dental chair.

The proposed devices include two models, U300 and U500. Both of the two models mainly consist of instruments, instrument arm tray, cabinet group, operation light, operation light arm, assistant position, pedal switch, and patient chair.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 2005 +COOR.1 (2006) + CORR.2 (2007), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- ISO7494-1: 2004, Dentistry - Dental units - Part 1: General requirements and test methods. ISO7494-2: 2003, Dentistry - Dental units - Part 2: Water and air supply.
- ISO 6875: 2011, Dentistry -- Patient chair
- ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item		Proposed Devices	Predicate Device
Product Code		EIA	EIA
Regulation No.		21 CFR 872.6640	21 CFR 872.6640
Class		1	1
Intended Use		The Dental Unit is intended to supply power to and serve as a base for dental devices; and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.	The Dental Unit with Chair is intended to supply power to and serve as a base for dental devices and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.
Features	Operating Light	Halogen	LED
	Connection Joint	Comply with ISO9168	Comply with ISO9168
	Water Heating	Yes	No
Operation Method		Control Panel / Assistant Control Panel / Foot Controller	Control Panel / Assistant Control Panel / Foot Controller
Power Supply		110V	110V
Frequency		50/60Hz	50/60Hz

Power (with dental chair)		900VA	400VA
Pressure of Water Supply		200 kPa ~ 400 kPa	0.2MPa-0.4MPa
Pressure of Air Supply		≥550 kPa	0.55MPa
Dental Chair	Loading Capacity	135Kg	200kg
	Movement Range (Chair)	420-820 MM	390mm-740mm
	Movement Range (Backrest)	0°~ 80°	1°-70°
	Movement Range (Headrest)	200MM	150mm
Accessories can be attached to the device		Handpiece / Scaler / Curing Light / Syringe	Handpiece / Scaler / Curing Light / Three-way-Syringe
Performance Standards		Comply with ISO7494-1, ISO7494-2 and ISO6875	Comply with ISO7494-1, ISO7494-2 and ISO6875
Rate of Water Suction	Suction	≥ 1L/min	1 L/min
	Silva Ejector	> 750mL/min	750ml /min
Electrical Safety		Comply with IEC 60601-1	Comply with IEC 60601-1
EMC		Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Patient Contact Material		Armrest: PU Leather for patient chair: PVC Syringe: Stainless steel Tubes: TPU	PU, PVC, Polyamide, ABS, Stainless steel

The proposed devices, Dental Unit U300 and U500, are determined to be Substantially Equivalent (SE) to the predicate device, Dental Unit with Chair S2310 (K130410), with respect to intended use, technological characteristics and principles of operation.